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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/022,182      | 12/14/2001  | Steven M. Bowman     | 022956-0074         | 1527             |

21125 7590 06/16/2005

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EXAMINER

FUBARA, BLESSING M

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1618

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/022,182

Applicant(s)

BOWMAN ET AL.

Examiner

Blessing M. Fubara

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 and 16-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 16-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Examiner acknowledges receipt of amendment and remarks filed 02/17/05. Claims 1-8 and 16-24 are pending.

#### ***Claim Rejections - 35 USC § 112***

1. The rejection of claims 7 and 8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

#### ***Claim Rejections - 35 USC § 102***

2. The rejection of claims 1, 2, 5, 7, 8 and 24 under 35 U.S.C. 102(b) as being anticipated by Seare, Jr. (US 5,589,176) is withdrawn because the amended claim 1 and 24 now recite density of the mesh and Seare while relating density of the SRO-CPMF with percentage porosity of the porous portion of device (column 7, lines 1-3) does not specifically disclose the density of the porous open-cell comprising continuously interconnected pores.

The rejection of claims 1, 2, 5, 7, 8 and 24 under 35 U.S.C. 102(b) as being anticipated by Polson et al. (US 5,487,897) is withdrawn because Polson does not disclose the density of the porous foam-like structure (column 17, lines 27 and 28).

3. The rejection of claims 1-8 and 16-24 under 35 U.S.C. 102(e) as being anticipated by Vyakarnam et al. (US 6,306,424) is withdrawn because while Vyakarnam discloses that cells are seeded on meshes at a density of 40,000 cells/well, Vyakarnam does not specifically disclose mesh density.

Claims 1 and 24 are amended to recite mesh density. The prior art of record do not disclose mesh density. However, in the absence of a showing, recitation of mesh density does

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not patentably distinguish the claimed invention over the prior art. New rejections follow in light of the amendment.

*Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-8 and 16-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vyakarnam et al. (US 6,306,424)

Vyakarnam discloses administration of a composition for tissue repair and regeneration (column 1, lines 8-14). Vyakarnam's composition comprises a foamed composition that is comprised of biocompatible and bioabsorbable polymer foam and where the biocompatible foam has interconnecting pores and comprises polyesters; and the composition comprises active agents selected from anti-infective, hormones, analgesics, anti-inflammatory agents, growths factors, chemotherapeutic agents, anti rejection agents, prostaglandins and combinations (claims 1-39; column 12, lines 43-56; column 4, lines 26-37; column 25, lines 13-16). Vyakarnam does not disclose the density of the mesh. And regarding the mesh density, there is also no demonstration that a mesh density of 12-80% provides any critical function to the foam. But, Vyakarnam discloses that cells can be seeded on meshes at a density of 40,000 cells per well. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer bioabsorbable foam for tissue repair and determine the repair process by

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cell proliferation. A mesh density of 12-80% is not inventive over the Vyakarnam in the absence of a showing.

6. Claims 1, 2, 5, 7, 8 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seare, Jr. (US 5,589,176).

Seare, Jr. discloses porous medical device that comprises continuously interconnected pores, which utilizes at least one removable open-cell porous mold form (abstract). The porous medical device can be implanted in the body to promote new loose tissue and new vessel ingrowth (column 3, lines 41-45). The porous medical device can be a breast implant made of polymethacrylate and formed with the desired curvature (column 12, lines 29-36). The porous medical device can also be a drug delivery system for implantation and some of the drugs that may be incorporated are antibiotics (column 14, lines 26-40). Polyglycolic acid or polylactic acid material (column 15, lines 9 and 10) may be used as the polymer for the implant. Tissue such as bone marrow, liver, pancreas, collagen and tissue cell can be transplanted (column 9, lines 41-45) with the aid of the medical device of Seare, Jr. Seare, Jr. while relating density of the SRO-CPMF with percentage porosity of the porous portion of device (column 7, lines 1-3) does not specifically disclose the density of the porous open-cell comprising continuously interconnected pores.

The instant method of treating tissue injury comprises providing biocompatible, bioabsorbable polymeric foam. The device of Seare, Jr. is administered to the desired site and the device also assumes the structure of the site or target of interest. While Seare, Jr. does not specifically use the term foam, the disclosure that the device is porous and of an open-cell structure implies a structure that is foam. Therefore, it would have been obvious to one of

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ordinary skill in the art at the time the invention was made to administer porous medical device that comprises continuously interconnected pores, which utilizes at least one removable open-cell porous mold form. The density of the mesh is not inventive over the prior art in the absence of a showing.

7. Claims 1, 2, 5, 8 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polson et al. (US 5,487,897).

Polson discloses a foamed composition (abstract; column 4, lines 43-55; columns 7 and 8) that comprises polyesters (column 6, lines 10-22 and claim 30) and biologically active agent that include antibacterial agents, antifungal agents, anti-inflammatory agents, anti-neoplastic agent and growth factors (column 10, lines 12-43). The disclosure of Polson meets the limitation of the claims.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Felt et al. (US 6,306,177) discloses a system for repairing tissue in situ (abstract; columns 7 and 8; column 11, lines 1-7; column 25, lines 31-38). MacPhee et al. (US 6,197,325) discloses method of repairing tissues by administering sealant compositions (abstract).

### *Response to Arguments*

9. Applicants' arguments filed 02/17/2005 have been fully considered but they are not persuasive.

Regarding Seare: It is noted that applicants' foam is formed by lyophilization/freeze drying (Example 1). In the same way, Seare's porous structure is formed by supplying dry air and freeze-drying or vacuum desiccating (column 6, lines 31-35). Therefore, applicants' foamed material reads on Seare's porous material.

Regarding Polson: Polson's support layer is a porous form-like structure (column 17, lines 27 and 28).

Regarding Vyakarnam: Vyakarnam discloses administration of a composition for tissue repair and regeneration (column 1, lines 8-14) and the composition comprises a foamed composition that is comprised of biocompatible and bioabsorbable polymer foam and where the biocompatible foam has interconnecting pores and comprises polyesters.

The difference between the cited references and the invention is the now added limitation of mesh density of about 12-80%. In the absence of a showing of unexpected results, the mesh density of about 12-80% is not critical over the prior art.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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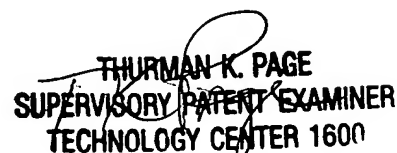
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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